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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/477,392	01/04/00	HEINTZ	N V0139/7038-(

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EXAMINER	
ZEMAN,R	
ART UNIT	PAPER NUMBER
1645	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/477,392	Applicant(s) HEINTZ ET AL.	
	Examiner Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-23 and 29* is/are pending in the application.

4a) Of the above claim(s) *17-23 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on 7-26-2001 is acknowledged. Claims 1, 6 and 7 have been amended. Claims 1-23 and 29 are currently pending. Claims 17-23 and 29 have been withdrawn from consideration. Claims 1-16 are currently under examination.

Drawings

Formal drawings were received on 7-30-2001 and have been forwarded to the draftsman.

Claim Rejections Withdrawn

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the phrase "deletions, additions and substitutions of (a) which code for a polypeptide having RIP60 activity" is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use inconsistent use of the terms "molecule" and "molecules" is withdrawn in light of the amendment thereto.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by reciting improper Markush language is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-16 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record.

Applicant argues:

1. Claim 1, as amended, now satisfies the written description requirement.

2. Example 9 of the Written Description Guidelines (published in the Federal Register on January, 5, 2001) indicates that a claim relating to an isolated nucleic acid that specifically hybridizes under highly stringent conditions to a complement of a particular sequence satisfies both the species and genus written description requirement

3. SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5 and SEQ ID NO:50 each serve as actual reductions to practice of a species.

4. With regard to the genus analysis substantial variation among species molecules that hybridize to the aforementioned nucleic acids would not be expected given the hybridization conditions, the requisite coding function of DNA and the skill and knowledge in the art.

5. Claim 1 is further encompasses nucleic acids that differ from the genus of hybridizing molecules due to degeneracy of the genetic code and that code for polypeptides having RIP60 activity.

6. The Guidelines indicate that a claim to a protein comprising a particular amino acid sequence is adequately described when each member of the genus shares a common feature.

Applicant's arguments have been fully considered and are deemed non-persuasive.

As detailed in the previous Office action the specification doesn't adequately describe what encompasses neither "RIP activity" nor "stringent conditions". The specification does not define "RIP60 activity". The passage cited by Applicant states "RIP60 activity intends a wide variety of activities and **can** include one or more of the following: DNA binding; protein multimerization; and nucleic acid looping". Said passage merely recites three possible activities of the RIP60 protein and is insufficient to define the metes and bounds of the claimed invention. Additionally, with regard to the definition of "stringent conditions", the passage of the specification cited by Applicant states that "stringent conditions as used herein refers, **for example**, to hybridization at 65 degrees C in hybridization buffer.....". Said passage merely recites parameters of one example of stringent conditions but does not define said term. Consequently, as detailed in the Previous Office action, the specification discloses SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:5 and SEQ ID NO:50 which corresponds to the cDNA/genomic DNA encoding the protein human RIP60 and nucleic acids encoding polypeptides with sequences corresponding to SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO:6 and SEQ ID NO:51. Said sequences meet the written description provision of 35 USC 112, first paragraph. However, said claims are directed to encompass all nucleic acid molecules which code for polypeptides that have RIP60 activity (including all mutants derived by deletions, additions and/or substitution): sequences that hybridize to SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:5 and SEQ ID NO:50 and nucleic acids encoding polypeptides with sequences corresponding to SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO:6 and SEQ ID NO:51, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a

recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

The rejection of claims 1-5, 11 and 14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record.

Applicant argues:

1. Claims 1-5 are drawn to nucleic acids that code for polypeptides having RIP60 activity. Claims 11 and 14 are drawn to vectors comprising said nucleic acids and host cells containing said vectors.

2. Examiner's assertion that "the resulting polyproteins may or may not possess any of the biological properties of RIP60 polypeptide" is moot since said claims recite having RIP60 activity as a limitation.

3. The specification defines (on page 21, lines 24-27) RIP60 activity as including one or more of the following activities: DNA binding; protein multimerization; and nucleic acid looping.

4. The specification details the mutation of several regions of the RIP60 polypeptide including the Z1 and proline rich region and the effects of said mutations on RIP60 activity. Applicant's arguments have been fully considered and deemed non-persuasive.

As detailed in the previous Office action the specification doesn't adequately describe what encompasses "RIP activity" nor "stringent conditions" (see above).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term "RIP60 activity" is maintained for reasons of record.

Applicant argues:

1. Specification defines (on page 21, lines 24-27) RIP60 activity as including one or more of the following activities: DNA binding; protein multimerization; and nucleic acid looping.

Applicant's argument has been fully considered and deemed non-persuasive.

The specification does not define "RIP60 activity". The passage cited by Applicant states "RIP60 activity intends a wide variety of activities and **can** include one or more of the following: DNA binding; protein multimerization; and nucleic acid looping". Said passage merely recites three possible activities of the RIP60 protein and is insufficient to define the metes and bounds of the claimed invention.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term "under stringent conditions" is maintained for reasons of record.

Applicant argues:

1. The specification defines stringent conditions as conditions that allow for homologs and alleles of RIP60 nucleic acids to be identified using hybridization assays (page 22, lines 9-18).

2. Specification provides an example of stringent conditions (page 22, lines 18-24).

3. The term stringent conditions is defined in the specification and is also known and practiced in the art on a routine basis and therefore is not indefinite.

Applicant's arguments have been fully considered and are deemed non-persuasive.

The passage specification cited by Applicant states that "stringent conditions as used herein refers, **for example**, to hybridization at 65 degrees C in hybridization buffer.....". Said passage merely recites parameters of one example of stringent conditions and is insufficient to define the metes and bounds of the claimed invention.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by referring to sequences listed in Table 1 within the specification is maintained for reasons of record.

Applicant argues:

1. The term "sequences having the accession numbers of Table 1" is defined in the specification.

2. Specification contains only one Table 1.

3. The courts have held that the specification can be referred to for the meaning of a claim term.

Applicant's arguments have been fully considered and are deemed non-persuasive.

While the specification may be referred to elucidate the meaning of a given claim term, claim limitations such as sequences must be recited in the claims.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the phrase "nucleotides which are not identical to" is maintained for reasons of record.

Applicant argues:

1. The amended claim rephrases the negative limitation as a positive one.

Applicant's argument has been fully considered and deemed non-persuasive.

The phrase "other than the exact sequence" recited in the amended claim is still a negative limitation

The rejection of claims 6 and 9-10 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term "unique fragments" is maintained for reasons of record.

Applicant argues:

1. The specification defines "unique fragments" as a fragment that is a signature for the larger nucleic acid which in long enough to ensure that its precise sequence is not found in molecules within the human genome outside of the RIP60 nucleic acids defined by the invention (page 24, lines 9-11).

2. The American Heritage Dictionary defines unique as being one of a kind; without an equal or equivalent; unparalleled.

Applicant's arguments have been fully considered and are deemed non-persuasive.

The passage recited by Applicant is preceded by the phrase "**for example**". Said passage merely recites one example of a fragment. Additionally, said claim 6 recites "**a unique**

fragment". Said term suggests there is only one "unique fragment". As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1-3 and 6-9 under 35 U.S.C. 102(a) as being anticipated by Sulston et al. (Genome Research, Vol. 8 No. 11, 1998, pages 1097-1108) is maintained for reasons of record.

Applicant argues:

1. The cited reference does not disclose the claimed sequences.
2. Applicant was unable to search the website disclosed in cited reference for sequences.
3. The Genbank listing relied upon by Examiner has an availability date of 9-30-2000 which is after Applicant's priority date.

Applicant is reminded that the date of the publication disclosed in the Genbank listing is prior to Applicant's priority date (1998). Applicant has questioned the date when the sequences disclosed in the instant application were made publicly available. Said dates are currently being determined, but in the absence of evidence to the contrary, the Examiner continues to rely on the

reference date as evidence of sequence availability to the public. Consequently, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Sulston et al. (Genome Research, Vol. 8 No. 11, 1998, pages 1097-1108) is maintained for reasons of record.

Applicant argues:

1. The cited reference does not disclose the claimed sequences.

2. Applicant was unable to search the website disclosed in cited reference for sequences.

3. The Genbank listing relied upon by Examiner has an availability date of 9-30-2000 which is after Applicant's priority date.

Applicant is reminded that the date of the publication disclosed in the Genbank listing is prior to Applicant's priority date (1998). Applicant has questioned the date when the sequences disclosed in the instant application were made publicly available. Said dates are currently being determined as discussed above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7911. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
October 9, 2001